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08/908,469

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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 08/908,469 | 08/06/97 | BACA | M P1093P1 |
| | | | EXAMINER |

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HM21/0609

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| UNCLASS. S | PAPER NUMBER |
| ART UNIT | |

1642
1642

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DATE MAILED: 06/09/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on Application filed 8/6/97
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-42 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-42 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13::

Group I. Claims 1-31 and 33 are drawn to humanized anti-VEGF antibody, classified in Class 530, subclass 387.1.

Group II. Claims 34-38 are drawn to an isolated nucleotide sequence, classified in Class 536, subclass 23.1.

Group III. Claims 39-42 are drawn to a method of inhibiting VEGF-induced angiogenesis classified in Class 424, subclass 130.1

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-II as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

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shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody products as claimed can be used in a materially different process such as affinity chromatography.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is subject to election of species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising anti-VEGF antibodies with different structures and therefore different functions wherein the antibodies are (a) the parent antibody (claims 1-13), (b) a variant of the parent antibody with a mutated heavy chain variable region (claims 14-31 and 33).

6. Group I is subject to election of species if species (a) of Section 5 is elected.

Claims 1 and 2 are generic to a plurality of disclosed patentably distinct species comprising heavy chain variably domains with different amino acid sequences which have therefore different structures and different functions wherein the variable regions comprise (a) SEQ ID NOs: 128, 2 and 129 (claims 6 and 7), (b) SEQ ID NO: 125 (claim 13) and (c) SEQ ID NOs: 1, 2 and 3 (claim 8).

7. Group I is subject to election of species if species (a) of Section 5 is elected.

Claims 1 and 2 are generic to a plurality of disclosed patentably distinct species comprising light chain variably domains with different amino acid sequences

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which have therefore different structures and different functions wherein the variable regions comprise (a) SEQ ID NOs: 4, 5 and 6 (claims 9 and 10), (b) SEQ ID NO: 124 (claim 12) and (c) SEQ ID NOs: 1, 2 and 3 (claim 8).

8. It is noted that claim 11 will be examined if species (a) of Section 6 and species (a) of Section 7 are elected.

9. Group I is subject to election of species if species (b) of Section 5 is elected..

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising heavy chain variable domains with different amino acid sequences which have therefore different structures and different functions wherein the variable regions comprise (a) substitutions in CDRH1 (claims 18 and 23), (b) substitutions in CDRH3 (claims 19 and 24), (c) substitutions in both CDRH1 and CDRH3 (claim 20).

10. Group I is subject to election of species if species (b) of Section 5 is elected.

Claims 14 and 25 are generic to a plurality of disclosed patentably distinct species comprising light chain variable domains with different amino acid sequences which have therefore different structures and different functions wherein the variable region comprises (a) SEQ ID NOs: 124 (claim 26), (b) SEQ ID NO: 115 (claim 27).

11. Group III is subject to election of species.

Claim 39 is generic to a plurality of disclosed patentably distinct species comprising different diseases with different etiologies and treatments that require materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the diseases are (a) tumor, (b) retinal disorder.

12. Should applicant traverse on the ground that the species are not patentably

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distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

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(703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4065.

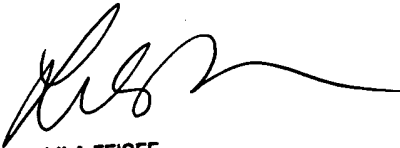
Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar

May 18, 1998



LILA FEISEE
SUPERVISORY PATENT EXAMINER